4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0031]

Best Practices for Development and Application of Disease Progression Models; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research, and Center for Biologics Evaluation and Research, are announcing a public workshop entitled "Best Practices for Development and Application of Disease Progression Models." The purpose of this public workshop is to discuss the best practices for developing disease progression models and their application to support drug development decisions, share experiences and case studies that highlight the opportunities and limitations in the development and application of disease progression models including models for natural history of disease and clinical trial simulations, and discuss the knowledge gaps and research needed to advance the development and use of disease progression models.

DATES: The public workshop will be held on November 19, 2021, from 9:30 a.m. to 2:30 p.m., Eastern Time. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: This workshop will be virtual only.

FOR FURTHER INFORMATION CONTACT: Maryanne Dingman, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8777; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

Under the FDA Reauthorization Act of 2017 (Pub. L. 115-52), FDA agreed, in accordance with section I of the Prescription Drug User Fee Act (PDUFA) VI Performance Goals, "Ensuring the Effectiveness of the Human Drug Review, part J, Enhancing Regulatory Decision Tools to Support Drug Development and Review," to hold several workshops to identify best practices for model-informed drug development. This workshop, "Best Practices for Development and Application of Disease Progression Models," fulfills FDA's performance commitment under PDUFA VI.

II. Topics for Discussion at the Public Workshop

The following topics will be discussed at the public workshop:

- Role of disease models in drug development and regulatory review;
- Lessons learned from past experiences of applying disease models in drug development;
- Best practice considerations for disease modeling to support drug development and regulatory decisions; and
- Best practice considerations for clinical trial simulations based on disease progression/natural history models to support drug development and regulatory decisions.

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register by November 9, 2021, at https://go.usa.gov/xMxPZ.

If you need special accommodations due to a disability, please contact Maryanne Dingman (see FOR FURTHER INFORMATION CONTACT) no later than November 9, 2021.

Streaming Webcast of the Public Workshop: This public workshop will be webcast. A live webcast of this workshop will be available at https://go.usa.gov/xMxPZ on the day of the workshop.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It will also be accessible at https://go.usa.gov/xMxPZ.

Dated: September 28, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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